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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)				
		KARAG-007B2				
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United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	10/614,646		07/07/2003			
on11/20/07	First Named I	nventor .				
Signature Belliam MULT	Hampar	ezian				
	Art Unit Examiner		iminer .			
Typed or printed nameBethany Miles	1618 Zo		hreh A. Fay			
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.						
This request is being filed with a notice of appeal.						
The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.						
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assignee of record of the entire interest.			nature			
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.	<u>Kit</u>	M. stetin				
(Form PTO/SB/96)		Typed or	printed name			
attorney or agent of record.  Registration number 29445	(91	9) 855_124	6			
Registration number 29445	. (949) 855–1246 Telephone number					
attorney or agent acting under 37 CFR 1.34.						
	11/	20/07				
Registration number if acting under 37 CFR 1.34	-	C	Date			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.						

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Application No.: 10/614,646

Pre-Appeal Brief in Response to Office Action of July 26, 2007

Attorney Docket: KARAG-007B2



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Hampar L. Karagoezian	)	Confirmation No.	7637
Serial No.:	10/614,646	)	Art Unit:	1618
Filed:	July 7, 2003	)	Examiner:	Zohreh A Fay
For:	Synergistic Antimicrobial Ophthalmic and Dermatologic Preparations Containing Chlorite and Hydrogen Peroxide	) ) )		·

## **Pre-Appeal Brief Request for Review**

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action of July 26, 2007, Applicant is submitting a notice of appeal and a request for a pre-appeal brief conference.

## Reasons for Request for Review

Applicant respectfully submits that the Examiner has erred in finding Claims 1-7 and 10-18 unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 4,574,084 to Berger in view of U.S. Patent No. 5,782,992 to Frangione. The Examiner cites Berger as teaching an aqueous composition containing chlorite and a peroxy compound, and looks to Frangione as teaching the addition of lubricating polymers and surfactants into the composition. *See* page 3 of Office Action dated January 22, 2007. The Examiner concludes that as Applicant is "using the same composition as the prior art, therefore it is expected that the prior art composition would have the same characteristics as the claimed composition" (*See* page 2, second full paragraph, of Office Action mailed on July 26, 2007.)

Application No.: 10/614,646

Pre-Appeal Brief in Response to Office Action of July 26, 2007

Attorney Docket: KARAG-007B2

However, Applicant respectfully submits that the Examiner has failed to make a proper *prima facie* case for the rejection of the claims, as the disclosure of Berger and even Frangione in fact *teach against* the preparation of a composition that "remains intact <u>without</u> <u>degrading the chlorite compound into chlorine dioxide during storage at room</u> <u>temperature</u>" (emphasis added), as required by claim 1 of the instant application.

Instead, the Berger patent is replete with statements indicating that the formation of chlorine dioxide provides the beneficial disinfecting property. See, e.g., Column 3, lines 41-43 ("...chlorine dioxide removal...leads to an undesired weakening of the system in the sense of the invention"); Column 5, lines 5-6 ("This finished solution contains approximately 100g of chlorine dioxide per liter."); Column 6, lines 21-30 ("...chlorine dioxide, which is highly effective for disinfection purposes, is formed...The finished solution generally contains 8 to 15% by weight of chlorine dioxide, the range 10 to 12% by weight being regularly particularly advantageous."); Column 9, lines 11-28 ("...the stabilized, modified, aqueous chlorite solution according to the invention can be advantageously used wherever it is to lead to an oxidative action, particularly due to the formation of chlorine dioxides...A particular advantage of the chlorite solution according to the invention is that it generally permits a 100% conversion of the chlorite into chlorine dioxide in a wide pH-range...").

It is known within the art that acidification of an aqueous sodium chlorite solution generates chlorine dioxide and the color of the resulting solution becomes greenish, exactly as is described in the Berger patent. *See, e.g.*, Column 4, lines 23-33 ("After some time, there is a yellow-brown coloring as a result of the proportionally released chlorine dioxide...after a short time the desired greenish coloring of the clear aqueous solution reappears. This means that...the chlorite solution always re-forms chlorine dioxide..."); Column 2, lines 24-29 ("According to the invention...a weak acid aqueous solution of a peroxy compound...is provided and into this solution is metered an aqueous solution of a chlorite until the pH-value of 7 is exceeded, accompanied by the formation of a greenish solution."). Frangione also teaches the desirability of providing chlorine oxides in a solution.

Application No.: 10/614,646

Pre-Appeal Brief in Response to Office Action of July 26, 2007

Attorney Docket: KARAG-007B2

See, e.g., Abstract ("The oxidizing agent of this invention preferably is selected from the group comprising chlorine oxides.")

In contrast, the presently claimed invention describes a chlorite/peroxide composition at neutral pH that *produces no chlorine dioxide*. The fact that the instantly claimed composition does not generate chlorine dioxide is further verified by Experiments 1-7 in the instant specification, which show that spectrophotometric analysis of the compositions indicated the complete absence of chlorine dioxide formation. The presence of chlorine dioxide would make the solution both irritating and toxic for use in the eye or on the skin, and thus has been specifically avoided in the composition of the invention. It has been shown that exposure of chlorine dioxide of greater than 0.1 ppm for more than a few hours in a contact lens disinfection system causes the contact lenses to become distorted while also enhancing the deposition of proteins on the contact lens, making them non-useable.

Accordingly, the claimed composition is not the "same" as that of Berger, because the chlorite in the composition <u>does not degrade into chlorine dioxide</u>, in contrast to the preferred embodiments of Berger. Furthermore, one of ordinary skill in the art would not have been motivated to combine the teachings of Frangione with those of Berger to somehow create a composition without chlorite degradation, because such a composition would <u>directly contradict</u> the teachings of Berger that indicate the desirability and even necessity of chlorine dioxide generation. Thus, one of ordinary skill in the art would not have been motivated to combine the cited references to arrive at the claimed composition, because the references clearly *teach against* the desirability of providing such a composition.

Applicant thus respectfully submits that the Examiner has erred in finding a *prima* facie case of obviousness over the Berger and Frangione references, because one of ordinary skill in the art would have been taught away by the disclosures therein from forming the composition as claimed. Accordingly, Applicant respectfully requests withdrawal of the rejection of at least independent Claim 1 under 35 U.S.C. § 103(a) over Berger and

•Application No.: 10/614,646

Pre-Appeal Brief in Response to Office Action of July 26, 2007

Attorney Docket: KARAG-007B2

Frangione. Claims 2-7 and 10-18 depend from claim 1, and thus are believed to be allowable

for at least the same reasons as claim 1.

## Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. § 103, and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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